

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEETING OF THE  
NATIONAL HUMAN RESEARCH PROTECTIONS ADVISORY COMMITTEE (NHRPAC)

MONDAY, JULY 30 & TUESDAY, JULY 31, 2001

THE DOUBLETREE HOTEL  
1750 ROCKVILLE PIKE  
ROCKVILLE, MARYLAND, 20852  
301/468-1100

AGENDA

Monday, July 30, 2001

|                     |   |
|---------------------|---|
| 8:30am – 8:45am     | DEPARTMENT OF HEALTH AND HUMAN SERVICES &<br>HUMAN SUBJECT PROTECTIONS<br><b>Arthur Lawrence, Ph.D.</b><br>Acting Principal Deputy Assistant Secretary for Health     |
| 8:45am – 9:15am     | THE PERILOUS INTERSECTION OF PROTECTING HUMAN RESEARCH<br>SUBJECTS AND CONFLICTS OF INTEREST<br><b>Michael Wood, M.D.</b><br>President and CEO<br>The Mayo Foundation |
| 9:15am – 9:30am     | WELCOME: OVERVIEW OF MEETING<br><b>Mary Faith Marshall, Ph.D.</b><br>Chairperson, NHRPAC  |
| 9:30am – 10:30am    | FINAL REVIEW & APPROVAL OF NHRPAC RESPONSE TO<br>FINANCIAL RELATIONSHIPS INTERIM GUIDANCE<br><b>Mark Barnes, J.D.</b><br>Chairperson, Working Group                   |
| 10:30am – 12:30pm   | UPDATE: CHILDREN'S WORKGROUP<br><b>Alan Fleischman, M.D.</b><br>Chairperson, Working Group  |
| [10:30am – 10:45am] | BREAK   |
| 12:30pm – 1:30pm    | LUNCH - On your own   |

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|-----------------|--|----------|
| 1:30pm – 3:30pm | THE OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP)   |          |
|                 | <i>Introduction</i>  | [10 min] |
|                 | <b>Greg Koski, Ph.D., M.D.</b><br>Director, OHRP   |          |
|                 | <i>Education</i>   | [15 min] |
|                 | <b>Jeffrey Cohen, Ph.D.</b><br>Director, Division of Education                                     |          |
|                 | <i>Assurance</i>   | [15 min] |
|                 | <b>George Gasparis, Acting Director,</b><br>Division of Assurances and Quality<br>Improvement      |          |
|                 | <i>Compliance</i>  | [15 min] |
|                 | <b>Kristina Borrer, Ph.D.</b><br>Division of Compliance  |          |
|                 | <i>International</i>   | [10 min] |
|                 | <b>Melody Lin, Ph.D., Deputy Director and</b><br>Director, Office for International Activities     |          |
|                 | <i>Policy</i>  | [10 min] |
|                 | <b>Irene Stith-Coleman, Ph.D.</b><br>Director, Office of Policy, Planning, and<br>Special Projects |          |

3:30pm – 3:45pm

BREAK

3:45pm – 4:30pm

UPDATE AND DISCUSSION: THIRD PARTIES: RESEARCH SUBJECTS?

**Mary Kay Pelias, J.D., Ph.D.**  
Chairperson, Working Group

4:30pm – 4:45pm

CLOSING COMMENTS/ADJOURN

**Mary Faith Marshall, Ph.D.**

## Tuesday, July 31, 2001

8:30am – 8:45am

The Honorable Diana DeGette  
Congresswoman, Colorado

8:45am – 9:15am

HUMAN SUBJECT PROTECTIONS GENERAL ACCOUNTING OFFICE (GAO)

**Marcia G. Crosse, Ph.D.**  
Assistant Director, Health Care - Public Health Issues

9:15am – 9:45am

NATIONAL BIOETHICS ADVISORY COMMITTEE (NBAC)

**Marjorie Speers, Ph.D.**  
Acting Executive Director, NBAC

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|-------------------|--|
| 9:45am – 10:45am  | <p>HIPAA AND THE PRIVACY REGULATION:<br/>THE IMPLICATIONS FOR RESEARCH</p> <p><b>Julie Kaneshiro, M.A.</b><br/>Policy Analyst, Office of Science Policy<br/>National Institutes of Health</p>  |
| 10:45am – 11:00am | BREAK  |
| 11:00am – 12:30pm | <p>INFORMED CONSENT &amp; DECISIONAL CAPACITY</p> <p><b>Mary Faith Marshall, Ph.D.</b> - Overview</p> <p><b>Jeremy Sugarman, M.D., M.P.H., M.A.</b><br/>Director, Center for the Study of Medical Ethics<br/>and Humanities, Professor of Medicine and Philosophy<br/>Duke University Medical Center</p> <p><b>Don Rosenstein, M.D.</b><br/>Chief Psychiatry Consultation-Liaison Service<br/>National Institute of Mental Health</p> <p><b>Adil Shamoo, Ph.D.</b><br/>Department of Biochemistry and Molecular Biology<br/>University of Maryland School of Medicine</p> <p><b>Jim McNulty</b><br/>President, National Alliance for the Mentally Ill (NAMI)</p> |
| 12:30pm – 1:30pm  | LUNCH – on your own  |
| 1:30pm – 2:30pm   | <p>INFORMED CONSENT<br/>(CONTINUED)</p>  |
| 2:30pm – 4:30pm   | <p>UPDATE: SOCIAL SCIENCE</p> <p><b>Felice Levine, Ph.D.</b><br/>Executive Officer<br/>American Sociological Association</p> <p><b>Jeffrey Cohen, Ph.D.</b><br/>Director, Education, OHRP</p>  |
| [3:00pm–3:15pm]   | BREAK  |
| 4:30pm – 5:00pm   | <p>RECAP OF MEETING &amp; ACTION ITEMS</p> <p><b>Mary Faith Marshall, Ph.D.</b></p>  |
| 5:00pm            | ADJOURN  |